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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,470	02/26/2004	Satoshi Takasaka	PC 26222A	9092

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GLOBAL PATENT DEPARTMENT
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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
04/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/787,470	TAKASAKA, SATOSHI	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 9-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/22/2008 has been entered.

Response to Arguments

Applicants response filed on 2/5/2008 has been fully considered. In particular, Applicants argue over the 35 USC 103 rejections over Jain et al. in view of Cardenas et al. and further in view of Maw et al. Applicants argue that neither Jain or Cardenas disclose or suggest the use of sildenafil to alleviate somatic pain arising from spinal cord injury. Applicants further argue that Maw does not supplement the deficiencies of Jain or Cardenas.

In response to the above arguments, because Applicant's have amended the claims, the alleviation of somatic pain specifically is a claim limitation that was not previously addressed by the Examiner. It is noted that somatic pain is caused by pain receptors in the cutaneous tissues or musculoskeletal tissues. Taking into consideration what somatic pain is, the new claim limitation will be fully addressed in the following modified grounds of rejection below.

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al. (Brain Research 909, 2001, 170-78) in view of Cardenas et al. (Arch Phys Med Rehabil, Vol. 83, Dec. 2002).

Jain et al. teach that sildenafil is a cGMP PDE5 inhibitor that is useful in the treatment of pain, in particular peripheral antinociception (see in particular results and figures).

Jain et al. does not specifically teach that sildenafil or cGMP PDE5 inhibitors treat somatic pain in a patient suffering from spinal cord injury.

Cardenas et al. teach that chronic pain is associated with spinal cord injury (see whole document). Types of pain include musculoskeletal pain which is a type of somatic pain (see first paragraph on page 1708). Further, spasticity is associated with the musculoskeletal system in which muscles are continuously contracted and causes pain.

It is therefore obvious to one having ordinary skill in the art at the time the invention was made to combine the teachings of Jain et al., which teach that sildenafil is a cGMP PDE5 inhibitor and is useful in the treatment of peripheral pain, of which somatic pain is part of peripheral pain because it is not associated with the central

nervous system, with Cardenas et al. which teach that pain is associated with spinal cord injury. One having ordinary skill in the art at the time the invention was made would be motivated to combine the teachings of Jain et al., with Cardenas et al. because the prior art teaches that sildenafil treats peripheral or somatic pain and spinal cord injury is associated with pain.

Claims 2-3 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al. (Brain Research 909, 2001, 170-78) in view of Cardenas et al. (Arch Phys Med Rehabil, Vol. 83, Dec. 2002) as applied to claim 1 above, and in further view of Maw et al. (U.S. Patent 6,856,439).

Jain et al. and Cardenas et al. teach that sildenafil treats somatic pain and that pain is associated with spinal cord injury.

Jain et al. and Cardenas et al. do not teach the route of administration or the dosage of sildenafil.

Maw et al. teach a pharmaceutically active compound comprised of a cGMP PDE5 inhibitor that is used to treat various disorders, including female sexual pain disorder and sexual dysfunction due to spinal cord injury (Col. 25, lines 13-20). They further teach that the compound will be administered orally (encompassing claim 2, Col. 25, lines 52-53) and a dose range of tablets as being between 0.01 mg and 500 mg (encompassing claim 3; Col. 27, lines 30-31).

It is therefore obvious to one having ordinary skill in the art at the time the invention was made to combine the teachings of Jain et al., which teach that sildenafil is a cGMP PDE5 inhibitor and Cardenas et al. which teach that spinal cord injury is

associated with pain, with the teachings of Maw et al. which teach a composition comprised of a cGMP PDE5 inhibitor to treat various disorders, including female sexual pain disorder and sexual dysfunction in patients suffering from spinal cord injury. One having ordinary skill in the art at the time the invention was made would be motivated to combine the teachings of Jain et al. and Cardenas et al. with Maw et al. to obtain an efficacious compound to alleviate pain associated with spinal cord injury.

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617